## DE 3,430,631 A1

Job No.: 1505-91222

Translated from German by the Ralph McElroy Translation Company 910 West Avenue, Austin, Texas 78701 USA

## FEDERAL REPUBLIC OF GERMANY GERMAN PATENT OFFICE

#### PATENT NO. 34 30 631 A1

(Offenlegungsschrift)

Int. Cl.<sup>4</sup>:

A 61 L 2/18

Filing No.:

P 34 30 631.5

Filing Date:

August 20, 1984

Date Laid-Open to Public Inspection:

February 27, 1986

# METHOD AND DEVICE FOR CLEANING AND DISINFECTING ENDOSCOPIC INSTRUMENTS

Inventor(s):

Eugen Hohmann, Engineering

Graduate

6140 Bensheim, Germany;

Dr. Konrad Mund

8525 Uttenreuth, Germany;

Dr. Erhard Weidlich

8521 Spardorf, Germany

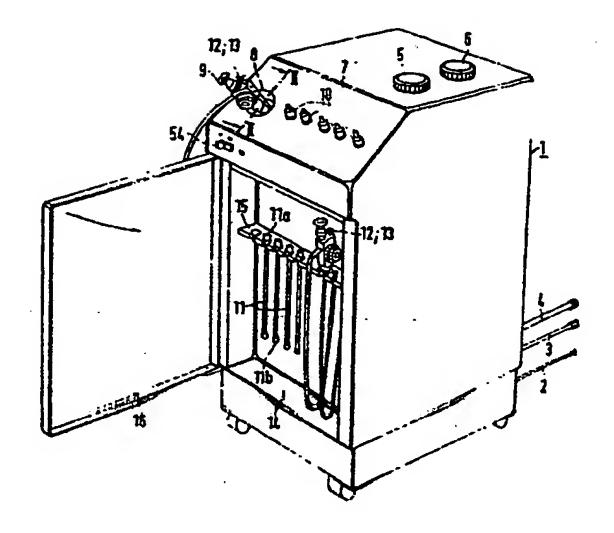
Applicant(s):

Siemens AG

1000 Berlin and

8000 Munich, Germany

To clean, disinfect, and sterilize endoscopic instruments, it is proposed that at least the components (9a, 12,13) of the instrument (9)that can be introduced into a body cavity be placed into a container (20)where they are rinsed and flushed for length of time T1 with a liquid which contains cleaning agents while said liquid is being continuously circulated. Subsequently, the components are again rinsed and flushed for length of time T2 with a liquid to which cleaning agents and/or sodium chloride (NaCl) have been added, with the liquid being circulated through an electrolytic cell (29) to which voltage is applied and the operation of which is based on the principle of electrolytic dissociation. Next, the components are again rinsed and flushed for length of time T3 with a liquid, with the liquid again being circulated through the electrolytic cell. During this time, the cell is operated at a reduced current density.



### Claims

- 1. A method for cleaning and disinfecting endoscopic instruments, characterized by the following process stages:
- a) at least the components (9a) of the instrument (9), including the working channels (12,13), which can be introduced into the body cavity are rinsed and flushed during length of time T1 with a liquid which contains cleaning agents while said liquid is being continuously circulated,
- b) subsequently, the components (9a,12,13) are again rinsed and flushed during length of time T2 with a liquid to which cleaning agents and/or sodium chloride (NaCl) have been added, with the liquid being circulated through an electrolytic cell (29) to which a voltage has been applied and the operation of which is based on the principle of electrolytic dissociation, and
- c) next, the components (9a,12,13) are again rinsed and flushed during time T3 with a liquid, with the liquid again being circulated through an electrolytic cell, which cell, however, is operated at a current density lower than the one used in the preceding process stage (b).
- 2. The method as claimed in Claim 1, characterized in that the liquid used is circulated from a storage container (24) and, after each process stage, is pumped into the waste line.
- 3. The method as claimed in Claim 1 or 2, characterized in that the liquid is passed through the electrolytic cell (29) even prior to being introduced into the storage container (24).
- 4. The method as claimed in one of Claims 1 through 3, characterized in that the liquid that is discharged from the container (24) at the end of the cleaning/rinsing cycle is also passed through the electrolytic cell (29).

- 5. The method as claimed in any one of Claims 1 through 4, characterized in that at the end of the last process stage (c), the polarity of the voltage that is applied to the electrolytic cell (29) is reversed, and optionally the direction of flow of the liquid through the cell (29) is also reversed.
- 6. A device for carrying out the method as claimed in any one of Claims 1 through 5, characterized in that a common housing (1) comprises a chamber (20) which has a spraying device (17 to 23) and an opening (8) that is accessible from the outside, into which opening the distal ends (9a) of the instruments (9) to be treated can be introduced, that within the housing (1), there is a container (24) which is connected to the chamber (20) and in which cleaning and rinsing liquid can be stored, that the housing (1) also comprises an electrolytic cell (29) to which an electric voltage can be applied and which includes an anode (35) and a cathode (36) and the inlet channel (39) of which can be connected to the feed line (25) for the liquid and the outlet channel (40) of which can be connected to the spraying device (17 through 23) in the chamber (20), and that, in addition, a circulating device (26) is made available, with which the liquid from the container (24) can be circulated through the cell (29) and the spraying device (17 to 23).
- 7. The device as claimed in Claim 6, characterized in that the housing (1) has a plurality of connector fittings (10) which are connected to a line segment (53) that leads to the spraying device (17 to 23), which connector fittings can be connected with their one ends (11a) to the connecting tubes (11) and with their other ends (11b) to the working channels (12,13) of the instruments (9).
- 8. The device as claimed in Claim 6 or 7, characterized in that in the upper front region (7) of a cupboard-like housing (1), there is at least one entry opening (8) for at least one instrument (9) as well as a plurality of connector fittings (10) and that below said front region, in a recess (14) which can be closed by a door (15)[sic; 16] or a similar cover, supports (15) for instruments (9) and/or connecting tubes (11) are provided.
- 9. The device as claimed in one of Claims 6 through 8, characterized in that the container (24) comprises a tube (19) with spray nozzles (18) that are distributed around the circumference, which tube, when inserted, surrounds the distal end (9a) of the instrument (9) and which is located at a certain distance from the wall (21) of the container, thereby forming a distributing chamber (20).
- 10. The device as claimed in any one of Claims 6 through 9, characterized in that the inside of the housing (1) comprises receptacles (49,50) for holding cleaning agents, on the one hand, and sodium chloride, on the other hand, and that the receptacles are connected to this container (24) by means of lines (51,52) and channels (17,23).
- 11. The device as claimed in Claim 10, characterized in that the receptacles (49,50) are fitted with closable filling vents (5,6) which are readily accessible from the outside.

And the second s

- 12. The device as claimed in any one of Claims 1 through 11, characterized in that it comprises a reversing switch (57,58,60) with which the voltage polarity of the electrolytic cell (29) can be reversed after conclusion of the program sequence.
- 13. The device as claimed in Claim 12, characterized in that the reversing switch (57,58,60) can also be used to reverse the direction of flow of the liquid through the cell (29) until the next program begins.
- 14. The device as claimed in any one of Claims 6 through 13, characterized in that the electrolytic cell (29) consists of an oblong body (30) which forms a flow-through chamber (31) in which two electrodes (35,36) that form an anode and a cathode are arranged face to face and at a close distance from each other, that an ion-permeable partition wall (32) is provided between the two electrodes which divide the hollow chamber (31) into an anolyte chamber (33) which holds the anode and into a catholyte chamber (34) which holds the cathode (36), that the anode and cathode chambers are connected to each other on one front end by a flow channel (38) and have on the other front end one terminal connector each (39,40), with the terminal connector that is adjacent to the anode forming the inlet and the other terminal connector (40) forming the outlet of the cell.
- 15. The device as claimed in Claim 14, characterized in that the anode and cathode chamber (33,34) are fitted with a turbulence grid (37).
- 16. The device as claimed in Claim 14, characterized in that the anode and cathode chambers (33,34) of the electrolytic cell (29) are separated from each other by a cation exchange membrane (32).
- 17. The device as claimed in Claim 16, characterized in that the resistance to the fluid flow of the membrane (32) is high when compared to that of the anode and cathode chambers (33,34).
- 18. The device as claimed in any one of Claims 14 through 17, characterized in that the membrane (32) is made of sulfonated polytetrafluoroethylene.
- 19. The device as claimed in Claim 14, characterized in that the electrodes (35,36) are porous and fill out the anode and cathode chamber.
- 20. The device as claimed in any one of Claims 6 through 13, characterized in that the electrolytic cell (29) consists of an oblong body (70) which forms a flow-through chamber (73) in which two electrodes (72,71) forming an anode and a cathode are arranged face to face and at a close distance from each other, with the surfaces of the electrodes that face away from the flow-through chamber (73) together with the body (70) forming flooding or ventilating channels (76).

- 21. The device as claimed in any one of Claims 13 through 18, characterized in that the electrodes (35,36,71,72) are made of activated titanium, preferably in the form of a lattice or an expanded metal.
- 22. The device as claimed in Claim 21, characterized in that the electrodes (35,36) are activated with precious metals..
- 23. The device as claimed in any one of Claims 14 through 22, characterized in that the electrodes (35,36) contain electrocatalysts.
- 24. The device as claimed in any one of the preceding claims, characterized in that during the cleaning phase, the cell (29) is operated at a current density of 80 mA/cm<sup>2</sup> to 120 mA/cm<sup>2</sup>, preferably at 100 mA/cm<sup>2</sup>, of electrode surface, and that during the rinsing phase, it is operated at a reduced current density, preferably between 5 mA/cm<sup>2</sup> and 20 mA/cm<sup>2</sup> of electrode surface.
- 25. The device as claimed in any one of Claims 1 through 24, characterized in that the effective electrode surface is in a range from 50 to 250 cm<sup>2</sup>, preferably 100 cm<sup>2</sup>.

For diagnosing gastric, intestinal, bladder, and bronchial disorders, endoscopic instruments are used, which, when inserted into the respective body cavities, allow a visual inspection of these organs. As a rule, the optical system of these instruments consists of glass fiber bundles which are used to transmit the image information and to fully illuminate the area examined. In addition, instruments of this type frequently have additional channels, hereinafter called working channels, which can serve to introduce, for example, rinsing liquids, to siphon off secretions, to introduce working instruments, for example, miniature forceps for tissue removal.

Because of the materials they are made of, endoscopic instruments of this type cannot be sterilized in hot-air sterilizers or autoclaves. As a result, the only alternative is to disinfect such instruments, which means that chemical disinfecting agents must be used. This type of disinfection has the disadvantage that it is possible for traces of disinfecting agents to adhere to the outside of the instrument and to the inside the working channels, which can lead to inflammation especially in allergic patients. A manually performed disinfection is also relatively time-consuming.

Thus, the invention described in Claims 1 and 6 aims at making available a method as well as a device by means of which endoscopic instruments can be cleaned and disinfected in a relatively simple but thorough manner.

The method according to the present invention as well as a practical example of a device for carrying out the method will be described in greater detail below with reference to the drawings. As can be seen:

Figure 1 shows a diagrammatic representation of an embodiment of the device according to the present invention,

Figure 2 shows a sectional view of a portion of the device seen in Figure 1 along line II/II in Figure 1,

Figure 3 shows a hydraulic block diagram of the device according to the present invention,

Figure 4 shows a longitudinal section through the electrolytic cell schematically shown in Figure 3,

Figure 5 shows an electrical block diagram of the device according to the present invention, and

Figures 6 and 7 show a different embodiment of the electrolytic cell.

Figure 1 shows a diagrammatic representation of the device according to the present invention. The device comprises a cupboard-like housing 1 in the form of an independent movable unit, on the back on which there are connecting lines 2, 3, and 4 for electric current, water inlet, and water outlet. On the top, two readily accessible closable filling vents 5,6 for a suitable cleaning agent, on the one hand, and sodium chloride (NaCl), on the other hand, are provided. The associated receptacles which are located in the inside of the housing are schematically represented in Figure 3 (reference numerals 49 and 50).

The upper front part of housing 1 is shaped like a lectern; this sloping housing section 7 has an opening 8 for introducing at least the distal end of an instrument 9 that is to be treated as well as five connector fittings 10 to which ends 11a of connecting tubes 11 can be connected by means of a quick connector -- details of which are not explained here -- and the other ends 11b of which connectors can be connected to various working channels 12,13 of the endoscopic instrument 9. As already mentioned earlier, these working channels can serve as channels for siphoning off secretions, for introducing rinsing fluid into the body cavity, etc. The connecting tubes 11 are stored in supports 15 which are located in a recess 14 of the housing. Recess 14 can be accessed by opening door 16. Reference numeral 54 denotes a start switch, with which the device, the electrical aspects of which will be explained in greater detail later, can be switched on and off.

Figure 2 shows a longitudinal section of a part of device 1 in the area of opening 8. Opening 8 provides access to an oblong tube-shaped rinsing chamber 17 into which the distal end 9a of instrument 9, when inserted, is immersed. Located inside rinsing chamber 17 is an inside tube 19 which is open toward the bottom and which has a plurality of spray nozzles 18 arranged along its circumference; said inside tube is supported by an outer tube 21 which is located at a certain distance from said inside tube, thereby forming a distributing chamber 20. Outer tube 21 has a connector fitting 22 for supplying rinsing liquid and a drainage channel 23, through which the rinsing liquid can drain after instrument 9 has been rinsed.

Figure 3 shows that below rinsing chamber 17, there is a container 24 into which the liquid can flow through drainage channel 23 of chamber 17 and be collected after the rinsing cycle is completed. Connected to container 24 is a line segment 25 which leads to a circulating pump 26 and a line segment 27 which leads to a suction pump 28 by means of which the liquid that has accumulated in container 24 -- when not used -- can be pumped into the waste line through water outlet line 4 (Figure 1). Fresh water is supplied via water inlet 3 (Figure 1) from the water mains.

The flow of water is controlled by means of magnetic valves 41 through 48. Reference numerals 49 and 50 denote the receptacles which are connected to filling vents 5,6 in Figure 1 into which sodium chloride in the form of a powder or a liquid, on the one hand, and a suitable cleaning agent (surfactant), also in the form of a powder or a liquid, on the other hand, are charged. Branching off common a line 51 are line segment 52 which is connected to the connector fitting 22 of rinsing chamber 17 and a line segment 53 which is connected to the individual connector fittings 10 which lead from the device to the outside of housing 1. The connecting tubes 11 which have already been described earlier can be connected to this connector fitting 10.

Before describing the process stages in greater detail, first the configuration of the electrolytic cell 29 will be explained in detail with reference to Figures 4, 6, and 7. As to the cell shown in Figure 4, housing 30 which is made of an insulating material and measures approximately 150 x 100 x 30 mm and which, in cross section, has a rectangular shape forms a hollow chamber 31 which is divided by a longitudinally extending ion-conducting membrane 32 into an analyte chamber 33 and a catholyte chamber 34. The membrane is preferably made of sulfonated polytetrafluoroethylene and can be described as a cation exchange membrane. Analyte chamber 33 comprises an anode 35, and catholyte chamber 34 comprises a cathode 36. The anode and the cathode are made of the same material, preferably of activated titanium. They may also be made of platinum foil, with one or more lattices of platinum or of platinum and iridium spot-welded thereon. As the embodiment shown in Figures 5 and 6 indicates, instead of the lattices, it is also possible to use expanded metals of titanium or tantalum which are coated with platinum black or platinum and ruthenium oxide. When such electrodes are used, the partition membrane between the anode and the cathode can be omitted.

Furthermore, it is also recommended that porous metals that are resistant to chlorine, such as Raney platinum and porous titanium sponge, or sintered metals which may optionally be coated with precious metal catalysts be used as the electrode material.

Reference numeral 37 denotes a turbulence grid which has been incorporated into the two chambers 33,34 and the function of which is to make the flow of water turbulent. The material used is preferably a fabric that is resistant to chemical attack, e.g., Teflon. If electrodes made of

expanded metal are used as shown in Figures 5 and 6, the turbulence grid can be omitted. The required turbulence of the water flowing through is ensured by the geometric configuration of the expanded metal

Anolyte chamber 33 is connected via channel 38 with catholyte chamber 34, thus allowing the liquid which flows in through channel 39 in the direction of the arrow to flow into the catholyte chamber after it has passed the anolyte chamber and to exit from the outlet channel 40 after having passed the catholyte chamber.

Another useful embodiment of an electrolytic cell is shown in Figures 6 and 7. The outside shape of the cell and the electrode configuration are basically identical to the embodiment shown in Figure 4, i.e., housing 70 made of insulating material holds two electrodes 71,72 which are spaced between 0.5 and 5 mm from each other and which can be energized with direct voltage. But in contrast to the embodiment described previously, there is no membrane which would divide the hollow or flow-through chamber 73. Accordingly, inlet channel 74 and outlet channel 75 are located opposite to each other. To achieve a more uniform flow of the liquid through the cell, it is useful if a plurality of inlet and outlet channels 74a,75a is provided as indicated by the broken lines. To improve the efficiency, it is also useful to include flooding and ventilating channels 76 between the electrodes and the housing, which channels are oriented in the direction of flow, as the longitudinal section in Figure 6 shows. The channels can also have the shape of a honeycomb; furthermore, within the scope of this invention, it is also possible to ensure the distance between the electrodes and the housing by means of other suitable measures. To obtain an optimum flow, it is beneficial if a distributing chamber 77,78 is provided upstream and downstream of the electrodes, which distributing chamber extends across the width of the electrodes.

Even though the efficiency of the last-described one-chamber cell is not as good as that of the two-chamber cell which was described first, the construction of the one-chamber cell and, in particular, the hydraulic connections are much simpler for this type of cell, as will be described later. If the two-chamber cell is used with extremely calcareous water (degree of hardness > 10° dH [German water hardness], it is recommended that an ion exchanger be connected downstream of the plant so as to avoid lime deposits along the partition wall.

The method according to the present invention comprises substantially three chronologically consecutive and automatically occurring steps:

- a) the primary or preliminary cleaning step,
- b) the subsequent cleaning step and disinfection, and
- c) the rinsing step.

In the primary or preliminary cleaning phase, container 24 is first filled with fresh water containing a cleaning agent. During the filling process, magnetic valves 42, 43, 44, and 47 are

7 1

open so that the fresh water containing the cleaning agent can flow into container 24. After magnetic valve 41 is closed, the cleaning process can be initiated. By means of circulating pump 26, cleaning liquid is continuously introduced over a period of time T1 of a few minutes from storage container 24 via line segment 52 into spray chamber 17, which causes the outside of the distal end 9a of endoscopic instrument 9 to be rinsed, on the one hand, and, at the same time, the inside of the working channels of the endoscopic instrument to be flushed via line segment 53 and the externally attachable tubes 11.

After this preliminary cleaning phase, the content of container 24 is drained by vacuum pump 28 into waste line 4. Subsequently, container 24 is again filled with liquid, but instead of cleaning agent, sodium chloride (from container 50) is added to the tap water. During the following circulating cycle, the liquid is additionally passed through electrolytic cell 29. In the course of this time T2, the cell is operated at a current density of up to 100 mA/cm<sup>2</sup> of electrode surface. Subsequently, the container is again drained and then refilled. During the following rinsing cycle during time T3, fresh water without any added substances is circulated from container 24 by means of pump 25 and through electrolytic cell 29, during which time the cell is operated at a reduced current density of 5 to 20 mA/cm<sup>2</sup> of electrode surface.

Each process stage takes only a few minutes. This is based on the assumption that the container content measures approximately 1 to 2 L and that, given an electrode surface of 100 cm<sup>2</sup>, the quantity recirculated measures approximately 600 mL/min.

The process sequence can be electrically controlled as illustrated in the block diagram shown in Figure 5, with an electronic control unit which is denoted by reference numeral 55 and which is preferably a microprocessor controlling the entire program sequence. After actuating the start switch 16, an electronic control 56 for electrolytic cell 29 is energized by means of switch S56. By way of reversing switches 57 and 58, the poles of the direct-voltage source of electronic control 56 are connected to the cathode and anode of cell 29.

Following each program sequence, the contacts of switches 57 and 58, on the one hand, and of an additional reversing switch 60, on the other hand, are reversed by means of a relay 59. Thus, it is possible, for example, for relay 59 to be picked up in odd-numbered program sequences and to be in normal position in even-numbered program sequences. By means of reversing switch 60, the direction of flow of the liquid through cell 29 reversed so that instead of valves 42,45, valves 43,44 are actuated; by means of reversing switches 57,58, the polarity of electrodes 35,36 is reversed. As explained in the description of the configuration of the electrolytic cell, just as the liquid entering the cell first comes into contact with the anode, the liquid entering the cell after reversal of the direction of flow will similarly also first come into contact with the electrode that now serves as anode. This is especially useful when working with

hard water since calcium carbonate not only precipitates in the liquid but also builds up as a layer on the cathode electrode.

Thus, the reversal causes a reconversion which can also be regarded as a regeneration of the cell. This ensures a constant functioning of the cell over a long period of time.

In case of an incident of malfunction, relay 61 interrupts the operation; this relay can also combined with an optical or acoustic malfunction display.

The electrical configuration can also be further simplified; thus, the number of magnetic valves V42, V43, V44, and V45 which serve to reverse the direction of flow in the electrolytic cell can be reduced by using four- or two-way valves.

As already explained earlier, the instrumental setup for controlling the flow of the medium can be considerably reduced when the cell seen in Figures 6 and 7 is used since no mechanism for reversing the direction of flow is required. As a look at the block diagram shown in Figure 5 indicates, valves V42 to V45 as well as the line segments to and from valves V43 and V44 can be omitted. Another look at the block diagram shown in Figure 5 also makes it clear that switch S22 can be omitted. All the other switching measures, including the polarity reversal of the electrodes, remain unchanged.

25 Claims7 Figures

